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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,255	07/03/2003	Mary Wilkes Eubanks		6006
7590	08/11/2005		EXAMINER	
Mary Wilkes Eubanks 8 Pilton Place Durham, NC 27705			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,255	EUBANKS, MARY WILKES	
	Examiner	Art Unit	
	Keith O. Robinson, Ph.D.	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-6 and 8-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 July 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>same</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Examiner acknowledges Applicant's election of Group II (claims 2-6 and 8-12) without traverse, the addition of new claims 13-17 and the cancellation of claims 1 and 7, filed 24 May 2005.

Claims 2-6 and 8-17 are under examination.

Claim Objections

2. Claims 3, 5, 6 and 9-17 objected to because of the following informalities:

- (a) in claim 3, line 1, "a plant" should be amended to – the plant --.
- (b) in claim 4, line 4, "a plant" should be amended to – the plant --.
- (c) in claim 4, line 5, -- the – should be inserted after "from" and before "seed".
- (d) in claim 6, line 3, "a plant" should be amended to – the plant --.
- (e) Claims 4-6 and 9-17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 2-6, 8-12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11 of U.S. Patent No. 5,750,828, published on May 12, 1998 and filed August 22, 1995.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods differ only in the scope of the claimed invention.

Eubanks (U.S. Patent 5,750,828, 1998) teaches in claims 1 and 6 the methods of crossing a *Tripsacum* plant with a teosinte (*Zea diploperennis*) plant to produce seed; harvesting the hybrid seed of said cross (claims 1 and 6); and growing a hybrid plant from said hybrid plant to maturity (claim 6); and the production of plant variants, derivatives, mutants and modifications of these plants by crossing maize plants with said hybrids; harvesting maize hybrid seeds from said cross (claim 6); and selecting progeny maize hybrid seeds for variance in the trait of resistance to corn rootworm (claim 9).

Eubanks (U.S. Patent 5,750,828, 1998) teaches in claims 2-5, dependent on claim 1; and claims 7-9 and 11, dependent on claim 6, hybrid plants, seeds, pollen,

tissue culture and derived variants and modifications thereof, which are drawn to claims 2-6, 8-12 and 14 of the instant specification.

The restriction fragments as claimed in claim 2 would occur during any form of mitotic or meiotic cell division and replication in the plant cell cycle and thus, would not make the instant claims non-obvious over Eubanks (U.S. Patent 5,750,828, 1998).

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to plants or parts thereof produced by crossing a *Tripsacum* plant with a teosinte plant to produce hybrids, wherein said hybrids are used to cross with other maize plants.

Claims 2-6 are broadly drawn to a plant containing one or more restriction fragments produced by crossing a *Tripsacum* plant with a teosinte plant wherein said plant is a hybrid that is grown to maturity and seed, pollen, and tissue culture of said plant.

The specification does not provide a written description of the claimed hybrid plant in terms of its genetic, morphological, and/or physiological characteristics. In addition, there is no written description of the *Tripsacum* or teosinte parents used to produce the claimed hybrid plant in terms of their genetic, morphological, and or physiological characteristics.

Claims 8-12 are broadly drawn to a maize plant, seed, pollen and tissue culture thereof, containing restriction fragments produced by crossing a *Tripsacum* plant with a teosinte plant to produce hybrid seed wherein a hybrid plant from said seed is grown to maturity and crossing said hybrid with a maize plant.

The specification does not describe the claimed maize plant or parts thereof in terms of its genetic, morphological, and/or physiological characteristics. There is no written description regarding the *Tripsacum* and teosinte parents that are used in the cross in terms of their genetic, morphological, and/or physiological characteristics nor is there a description of the hybrids produced from said cross with regards to their genetic, morphological, and/or physiological characteristics.

Claims 13-17 are broadly drawn to a maize plant distinguished by the presence of root aerenchyma (claim 13), tolerance to corn rootworm (claim 14), tolerance to drought (claim 15), improved grain quality (claim 16) or tolerance to acid soils (claim 17).

The specification does not describe any of the claimed plants with regard to their genetic, morphological, and/or physiological characteristics.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See

the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112, first paragraph – Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly drawn to plants or parts thereof produced by crossing a *Tripsacum* plant with a teosinte plant to produce hybrids, wherein said hybrids are used to cross with other maize plants.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 2-6 are broadly drawn to a plant containing one or more restriction

fragments produced by crossing a *Tripsacum* plant with a teosinte plant wherein said plant is a hybrid that is grown to maturity and seed, pollen, and tissue culture of said plant.

The specification does not provide guidance regarding the *Tripsacum* plant used in said cross in terms of its genetic, morphological, and/or physiological characteristics nor does it teach how to distinguish a *Tripsacum* plant used as a parent in the claimed method from other *Tripsacum* plants. The specification only teaches, "Crosses have been made using seven different *Tripsacums...*" (see page 22, first paragraph); however, there are eight *Tripsacum* plants listed and of these only four are identified by a particular cultivar or line name (i.e. *Tripsacum laxum* is identified as CEL 48770). There is no guidance in the specification regarding the teosinte plants used in said cross in terms of their genetic, morphological, and/or physiological characteristics. The specification only teaches, "...teosinte plants of *Zea diploperennis* originating from different populations in Jalisco, Mexico..." (see page 22, first paragraph) wherein said plants are given an identification number (i.e. plant 3-7) and an Accession number; however, plants 3-7 and 3-3 seem to have the same Accession number (i.e. 1250). In addition, the specification does not teach how to obtain said plants nor does it give a reference regarding the location of the depository that said Accession numbers are derived. Thus, one skilled in the art would not know how to make and/or use the invention as claimed without undue experimentation.

Claims 8-12 are broadly drawn to a maize plant, seed, pollen and tissue culture thereof, containing restriction fragments produced by crossing a *Tripsacum* plant with a

teosinte plant to produce hybrid seed wherein a hybrid plant from said seed is grown to maturity and crossing said hybrid with a maize plant.

The specification does not provide guidance regarding the *Tripsacum* plant used in said cross in terms of its genetic, morphological, and/or physiological characteristics nor does it teach how to distinguish a *Tripsacum* plant used as a parent in the claimed method from other *Tripsacum* plants. The specification only teaches, "Crosses have been made using seven different *Tripsacums...*" (see page 22, first paragraph); however, there are eight *Tripsacum* plants listed and of these only four are identified by a particular cultivar or line name (i.e. *Tripsacum laxum* is identified as CEL 48770). There is no guidance in the specification regarding the teosinte plants used in said cross in terms of their genetic, morphological, and/or physiological characteristics. The specification only teaches, "...teosinte plants of *Zea diploperennis* originating from different populations in Jalisco, Mexico..." (see page 22, first paragraph) wherein said plants are given an identification number (i.e. plant 3-7) and an Accession number; however, plants 3-7 and 3-3 seem to have the same Accession number (i.e. 1250). In addition, the specification does not teach how to obtain said plants nor does it give a reference regarding the location of the depository that said Accession numbers are derived. Thus, one skilled in the art would not know how to make and/or use the invention as claimed without undue experimentation.

Claims 13-17 are broadly drawn to a maize plant produced by the method of claims 8 or 10 wherein said plant is distinguished by the presence of root aerenchyma

(claim 13), tolerance to corn rootworm (claim 14), tolerance to drought (claim 15), improved grain quality (claim 16) or tolerance to acid soils (claim 17).

The specification does not provide any guidance regarding the making or use of the claimed plants nor does it provide any guidance regarding their genetic, morphological, and/or physiological characteristics. In addition, the specification does not teach how one skilled in the art would be able to differentiate the claimed plants from other plants having root aerenchyma, corn rootworm tolerance, or drought tolerance. Thus, one skilled in the art would not know how to make and/or use the invention as claimed without undue experimentation.

Interspecific crossing with *Zea* spp. and *Tripsacum* spp. is unpredictable. Bates et al (Proceedings of world-wide maize improvement in the 70's and the role of CIMMYT, April 22-26, El Batán, Mexico, 7 pp., 1974) teach that sexual barriers to wide hybridizations between *Zea* spp. and *Tripsacum* spp. include hybrid necrosis and pollen cross-incompatibility (see page 5-1B, line 1 to page 5 –2B, line 5). Eubanks (Economic Botany 49(2): 172-182, 1995) teaches that combinations of *Tripsacum* and teosinte may fail to hybridize, the ability to cross appear to be genotype specific, and that even if plants are recovered, they are often pollen sterile. (see Eubanks (1995), page 176, first column, line 12 to second column, line 7).

Given the claim breadth, the unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one of skill in the art to make and/or the invention as claimed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Eubanks (Theor. Appl. Genet. 94: 707-712, 1997). The claims read on plants produced by crossing a *Tripsacum* plant with a teosinte plant to produce hybrid seed and harvesting said seed; wherein said plant contains one or more restriction fragments.

Eubanks discloses hybrid plants produced by crossing a *Tripsacum* plant with a teosinte plant to produce hybrid seed and harvesting said seed. Eubanks also discloses said hybrid plants containing restriction fragments (see page 708, second column, third paragraph).

11. Claims 8-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Eubanks (Plant Patent 7,977, September 15, 1992). The claims read on plants produced by crossing a *Tripsacum* plant with a teosinte plant to produce hybrid seed and harvesting said seed, wherein said plant contains one or more restriction fragments, and then crossing said hybrid with a maize plant and plants derived from the hybrid/maize cross that possess distinguishing traits.

Eubanks discloses plants produced crossing a *Tripsacum*/teosinte hybrid with maize (see second column, lines 9-12) and the use of southern blotting (restriction

fragments) with said plants (see sixth column, lines 52-56). Eubanks also discloses plants with drought resistance (see second column, lines 10-11).

12. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Eubanks (Plant Patent 9,640, September 3, 1996). The claim reads on a maize plant having tolerance to corn rootworm, wherein said plant is produced by crossing a *Tripsacum*/teosinte hybrid with maize and wherein said plant has one or more restriction fragments.

Eubanks (1996) discloses *Tripsacum*/teosinte hybrid plants with resistance to corn rootworm, which would inherently possess one or more of the claimed restriction fragments (see second column, lines 29-31).

Conclusion

13. Claims 13, 16 and 17 are free of the prior art given the failure of the prior art to teach or suggest a maize plant that contains one or more restriction fragments, produced by crossing a *Tripsacum*/teosinte hybrid with a maize plant and wherein the hybrid from said cross is distinguished by the presence of root aerenchyma, improved grain quality and tolerance to acid soils, respectively.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

July 27, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

